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Gabriel Lopez

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May 19, 2005

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ORT-1222 USA DIV

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: David F. McComsey et al.

Serial No.: 10/606,422

Art Unit: 1653

Filed: June 26, 2003

Examiner: D. Luxton

Title: **SUBSTITUTED HETEROCYCLIC ACYL-TRIPEPTIDES USEFUL AS THROMBIN RECEPTOR MODULATORS**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**REPLY AND AMENDMENT**

Sir:

This is in reply to an Office Action dated January 19, 2005.

Cancel claims 11-17 and add claims 18-26. The claims appear on pages 4-6.

The claims are rejected under 35 USC 112 for lack of enablement, specifically because there is no showing of therapeutic efficacy. The rejection is traversed. The lack of a showing of therapeutic efficacy is not a basis for rejection under 35 USC 112. Further, the language of the rejection is virtually identical to that in the parent application with regard to the pharmaceutical composition claims therein. The Examiner's attention is directed to Paper No. 10, dated November 30, 2001, in parent application 09/565,715, now USP 6,747,127. The following is from the response thereto dated April 17, 2002:

Applicants have asserted that the in vitro assays for thrombin receptor binding and agonist activity in platelet aggregation provided in Tables 1 and 2 of the specification provide evidence that the compounds of claim 1 have utility as pharmaceutical compounds. Applicants respectfully submit that those skilled in the art are aware of the correlation of the inhibition of platelet aggregation as being predictive of a beneficial cardiovascular and other effect. Attached is "Structure-Activity Relationships of Pyrroloquinazolines as Thrombin Receptor Antagonists", by Ahn et al., which evidences the recognition of those skilled in the art of these facts. Accordingly, Applicants respectfully submit that they have met their burden under the statutes and as

**provided in MPEP section 2107.03, therefore, request that this rejection be withdrawn.**

On July 10, 2002, the Examiner withdrew the rejection ("The previously imposed §112 1st paragraph rejection is withdrawn.") Thus, the issue of therapeutic efficacy with regard to the invention, whether or not it is a proper basis for rejection and whether in the form of a composition (as in the parent application) or a method of treatment claim (as in the present application), has already been decided. A US patent is entitled to a presumption of validity. This presumption is stronger with regard to an issue that has been raised and overcome during prosecution, as is the case here. It is further noted that the Examiner who raised this issue in the parent application and then withdrew it is the also the present Examiner. Thus, this Examiner has already decided that lack of a showing therapeutic efficacy is not a basis for rejection herein.

The claims are also rejected under 35 USC 112 as being indefinite. The rejection is traversed. Regarding claim 10 (now claim 18), grammar suggests that it is the condition which is mediated. Regarding "modulation", it is not seen that the specific type of modulation is relevant to a rejection under 35 USC 112. Regarding claim 11, wound healing and tissue repair have been deleted from re-drafted claim 19 and new claim 26 has been added, supported by the paragraph bridging pages 1/2. The term "about" with regard to a range is not the basis for rejection under 35 USC 112. The Examiner's attention is directed to the recent Fosamax decision (*Merck v. Teva* (Fed. Cir. 2005), affirmed on appeal) in which there was an extensive discussion of the meaning of this word because applicant argued that it meant "exactly", based on text in the specification. The Court decided that the cited text was vague and that the ordinary meaning of "approximately" would apply. There was no issue of indefiniteness under the statute, merely what the meaning was for the patent in litigation. Further, this is term is commonly used in US patent claims to define the limits of a range. It is not indefinite under 35 USC 112. The term "composition" in claim 14 has been amended in re-drafted claim 22.

The Hungarian search report and all the other references stricken from the attachments to the IDS dated August 7, 2003 have been previously submitted in the parent application and are available both to the Examiner and to the public in the wrapper of said parent, now USP 6,747,127. In fact, the Examiner has already examined the references in the parent application and allowed claims to the compounds for which applicants are presently claiming methods of use. If the

application is still not available to the Examiner, it is requested that he advise applicants. It is requested that the Examiner return to applicants, fully initialed, the forms that were submitted on August 7, 2003.

It is further requested that the amendment be entered and that the Examiner reconsider the rejection in view of the amendment and remarks and that the case be passed to issue.

It is requested that the period for response be extended one month to May 19, 2005.

The Commissioner is hereby authorized to charge the extension fee of \$120 required by this paper to Deposit Account 10-0750/ORT 1222/GL

Respectfully submitted,



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